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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,533	09/12/2006	Calvin Bruce Harley	38797-8003.US00	8436

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EXAMINER

HOFFMAN, SUSAN COE

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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10/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/563,533

Applicant(s)

HARLEY ET AL.

Examiner

Susan Coe Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-18, 25, 26, 55 and 56 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15, 17, 18, 25, 26, 55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1-07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

1. The amendment filed September 7, 2007 has been received and entered.
2. Claims 1-11, 19-24 and 27-54 have been cancelled.
3. Claims 12-18, 25, 26, 55 and 56 are currently pending.

Election/Restrictions

4. Applicant's election without traverse of *Astragalus membranaceus* in the reply filed on September 7, 2007 is acknowledged.
5. Claim 16 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 7, 2007.
6. Claims 12-15, 17, 18, 25, 26, 55, and 56 are examined on the merits solely in regards to the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 55 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 55 is indefinite because it is unclear what alcohols are encompassed by "lower" alcohols.

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8. Claim 56 is indefinite because it is unclear what temperatures are encompassed by "heating."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 12-15, 17, 18, 25, 26 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Harley (US Pat. Pub. No. 2007/0154435).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Harley teaches compositions containing ingredients that induce telomerase at the levels claimed by applicant (see paragraph 46). The ingredients are extracted from A. membranaceus with alcohol and are included in compositions in the amounts claimed by applicant (see paragraphs 45 and 120).

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9. Claims 12-15, 17, 18, 25, 26, and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Chou (US Pat. No. 6,855,344) in light of Harley as evidence of inherent characteristics of Chou.

Chou teaches a method of treatment using a composition comprising an A. membranaceus extract. The extract is made by extracting the root of the plant with water or alcohol. The extract is used in the composition in amounts from 1 to 10% (see column 17, lines 31-43). The reference teaches that the active ingredient in the extract is astragaloside IV (see bottom half of column 19). The reference does not teach that the extract has the ability to induce telomerase as claimed by applicant. However, Harley teaches that astragaloside IV is able to induce telomerase as claimed (see paragraph 46). Thus, the extract taught by Chou would inherently have the ability to induce telomerase activity because it contains astragaloside. Therefore, the method of treatment taught by Chou would inherently induce telomerase in a patient because the method contacts cells and tissues with the astragaloside extract. Telomerase naturally occurring in these cells and tissues would be induced during contact with the extract.

10. Claims 12-15, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Binder et al. (US Pat. No. 5,770,578) in light of Harley as evidence of inherent characteristics of Binder.

Binder teaches a method of treatment using astragaloside IV (see claims). The reference does not teach that the extract has the ability to induce telomerase as claimed by applicant. However, Harley teaches that astragaloside IV is able to induce telomerase as claimed (see paragraph 46) and that astragaloside is an A. membranaceus root extract product (see paragraph 120). Thus, the extract taught by Binder would inherently have the ability to induce telomerase

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activity because it contains astragaloside. Therefore, the method of treatment taught by Binder would inherently induce telomerase in a patient because the method contacts cells and tissues with the astragaloside extract. Telomerase naturally occurring in these cells and tissues would be induced during contact with the extract.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 12-15, 17, 18, 55, and 56 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over CN 1079265 C.

CN '265 teaches a method of making a medicinal composition which contains membranous milk vetch root (*A. membranaceus*). The roots are crushed, mixed with 95% ethanol and then 75% ethanol and then heated and filtered. Additional ethanol is added to the residue and then heated and filtered. The two filtrates are mixed together to form the medicinal composition (see English abstract). The reference does not specifically teach that the composition is able to induce telomerase as claimed by applicant. However, the product of CN '265 is produced using a method that is extremely similar to the method claimed by applicant in claim 56. Thus, it is reasonable to conclude that the product taught in CN '265 is identical to the claimed product. Therefore, since the reference product and the claimed product reasonably

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appear to be the same product, the induction of telomerase would inherently occur when the prior art medicinal product is consumed. The induction of telomerase would be naturally occur in the telomerase found in the cells and tissues treated.

However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made because an artisan would reasonably expect that 75% ethanol could be substituted for 50% ethanol in the second ethanolic extraction step taught by the reference.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

12. Claims 12-15, 55, and 56 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Harley.

The teaching of Harley are discussed above. The reference does not specifically teach extracting the A. membranaceus in the manner claimed by applicant in claim 56. However, these are product-by-process claims. Regarding product-by-process claims, note that MPEP § 2113 states that:

"[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate...A lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972) ; In re Fessmann, 180 USPQ 324 (CCPA1974)... Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). "

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Harley teaches a product that reasonably appears to be the same product as claimed because the claimed product and the reference product are both able to induce telomerase activity. However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extracts as evidenced by their shared pharmaceutical characteristics.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

13. Claims 12-15, 55, and 56 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chou with Harley as evidence of inherent and/or intrinsic characteristics of Chou.

As discussed above, Chou teaches an extract from *A. membranaceus* that contains astragaloside IV. This extract of astragalus would naturally have the ability to induce telomerase as disclosed by Harley. Chou does not teach extracting the *A. membranaceus* in the manner claimed by applicant in claim 56. However, this is a product-by-process claim. Chou teaches a product that reasonably appears to be the same product as claimed because the claimed product and the reference product are both able to induce telomerase activity. However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the

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clearly close relationship between the extracts as evidenced by their shared pharmaceutical characteristics.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

14. Claims 12-15, 55, and 56 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Binder with Harley as evidence of inherent and/or intrinsic characteristics of Binder.

As discussed above, Binder teaches a composition comprising astragaloside IV. Thus, astragaloside IV would naturally have the ability to induce telomerase as disclosed by Harley. Binder does not teach extracting the astragaloside IV from *A. membranaceus* in the manner claimed by applicant. However, these are product-by-process claim. Binder teaches a product that reasonably appears to be the same product as claimed because the claimed product and the reference product are both able to induce telomerase activity. However, even if the reference extract and the claimed extract are not one and the same and there is, in fact, no anticipation, the reference extract would, nevertheless, have rendered the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the extracts as evidenced by their shared pharmaceutical characteristics.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

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Claim Rejections - 35 USC § 103

15. Claims 12, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harley.

The teaching of Harley are discussed above. The reference does not specifically teach using the A. membranaceus extract in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of extract to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

16. Claims 12, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou.

The teaching of Chou are discussed above. The reference does not specifically teach using the A. membranaceus extract in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by

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routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of extract to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

17. Claims 12, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binder.

The teaching of Binder are discussed above. The reference does not specifically teach using the astragaloside IV in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of astragaloside IV to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

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18. Claims 12, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over CN 1079265 C.

The teaching of this reference are discussed above. The reference does not specifically teach using the A. membranaceus extract in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of extract to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.


19. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Susan Coe Hoffman
Primary Examiner
Art Unit 1655